Replace the paragraph beginning at page 3, line 24 with:

This invention is directed to an improvement in the dispersibility of micronized particles through the specific selection of excipients and methodology necessary to recover the primary particles. Inherent in this approach is the ability to produce stable aqueous suspensions of micron or submicron particles of water insoluble or poorly water-soluble compounds. These particles, which are required in the practice of the present invention, can be prepared according to the methods disclosed in U.S. Pat. No. 5,091,187 and 5,091,188 as well as WO 98/07414, whose disclosure is incorporated herein by reference. Briefly, water insoluble or poorly soluble compounds are dispersed in an aqueous medium in the presence of surface modifying agents or combinations of agents of which at least one is a phospholipid adsorbed on the surface thereof. Particle fragmentation occurs when the aforementioned suspension is subjected to stress as a result of processing with the use of various methods known in the art including, but not limited to, sonication, milling, homogenization, microfluidization, and antisolvent and solvent precipitation. The particle so produced is referred to as a microparticle which is defined herein as a solid particle of irregular, non-spherical or spherical shape having a nominal diameter of from nanometers to micrometers on to which is adsorbed at least one surface modifying agent of which one is a phospholipid.

#2

Replace the paragraph beginning at page 4, line 24 with:

The present invention comprises a rapidly disintegrating solid dosage form for water insoluble compounds, which releases primary particles stabilized with one or more surface modifiers, including but not limited to phospholipids. Examples of some preferred water-insoluble drugs include antifungal agents, immunosuppressive and immunoactive agents, antiviral agents, antineoplastic agents, analgesic and antiinflammatory agents, antibiotics, antiepileptics, anesthetics, hypnotics, sedatives, antipsychotic agents, neuroleptic agents, antidepressants, anxiolytics, anticonvulsant agents, antagonists, neuron blocking agents, anticholinergic and cholinomimetic agents, antimuscarinic and muscarinic agents, antiadrenergic agents, antiarrhythmics, antihypertensive agents, hormones, and nutrients. A detailed description of these drugs may be found in Remington's Pharmaceutical Sciences, 18th Edition, 1990, Mack Publishing Co., PA. The concentration of the water insoluble ingredient in the aqueous suspension can vary between 0.1% w/w and 60% w/w, preferably between 5% w/w and 30% w/w.

#3

Replace the paragraph beginning at page 5, line 8 with:

The water insoluble compound is first prepared as an aqueous suspension in the presence of one or more surface stabilizing agents, of which at least one is a phospholipid. The phospholipid may be any natural or synthetic phospholipid, including but not limited to, phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, lysophospholipids, egg or soybean phospholipid or a combination thereof. The phospholipid may be salted or desalted, hydrogenated or partially hydrogenated or natural, semisynthetic or synthetic. The concentration of the phospholipid ingredient in the aqueous suspension can vary between 0.1% w/w and 90% w/w, preferably between 0.5% w/w and 50% w/w and more preferably between 1% w/w and 20% w/w.

Replace the paragraph beginning at page 5, line 17 with:

Examples of some suitable second and additional surface modifiers include: (a) natural surfactants such as casein, gelatin, natural phospholipids, tragacanth, waxes, enteric resins, paraffin, acacia, and cholesterol, (b) nonionic surfactants such as polyoxyethylene fatty alcohol ethers, sorbitan fatty acid esters, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, methylcellulose, hydroxycellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, noncrystalline cellulose, and synthetic phospholipids, (c) anionic surfactants such as potassium laurate, triethanolamine stearate, sodium lauryl sulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, negatively charged phospholipids (phosphatidyl glycerol, phosphatidylinositol, phosphatidylserine, phosphatidic acid and their salts), and negatively charged glyceryl esters, sodium carboxymethylcellulose, and calcium carboxymethylcellulose, (d) cationic surfactants such as quaternary ammonium compounds, benzalkonium chloride, cetyltrimethylammonium bromide, and lauryldimethylbenzyl-ammonium chloride, (e) colloidal clays such as bentonite and veegum. A detailed description of these surfactants may be found in Remington's Pharmaceutical Sciences, 18th Edition, 1990 Mack Publishing Co., PA; and Theory and Practice of Industrial Pharmacy, Lachman et al., 1986. The concentration of additional surfactants in the aqueous suspension can vary between 0.1% w/w and 90% w/w, preferably between 0.5% w/w and 50% w/w and more preferably between 1% w/w and 20% w/w. These surfactants may be either added initially during compounding or added post processing prior to freeze-drying or a combination of both depending on the nature, concentration and number of the surfactant(s).

Replace the paragraph beginning at page 6, line 29 with:

The resulting homogeneous suspension of microparticles stabilized by one or more surface modifiers is then mixed with bulking and/or releasing agents (dry or as an aqueous solution) and is then dried. The bulking or matrix-forming agent provides a mass in which the particles of drug are embedded or retained. The release agent assists in disintegration of the matrix when it contacts aqueous media. The bulking/releasing agents are chosen in order to produce a support matrix that, upon drying, will yield rapidly dispersible tablets that release the primary particles upon reconstitution in an aqueous medium. Examples of matrix-forming agents include (a) saccharides and polysaccharides such as mannitol, trehalose, lactose, sucrose, sorbitol, maltose, dextrose and maltodextrin; (b) humectants such as glycerol, propylene glycol, and polyethylene glycol; (c) natural or synthetic polymers such as gelatin, dextran, starches, polyvinylpyrrolidone, poloxamers, and acrylates; (d) inorganic additives such as colloidal silica, tribasic calcium phosphate and (e) cellulose based polymers such as microcrystalline cellulose, hydroxymethyl cellulose, hydroxypropyl cellulose, and methylcelluloses. Matrix forming agents may be added prior to producing the micronized particles of the therapeutic agent (formulation) or to the homogeneous suspension of microparticles prior to freeze-drying. The concentration of the matrix forming agents in the aqueous suspension can vary between 0.1% w/w and 90% w/w, preferably between 0.5% w/w and 50% w/w and more preferably between 1% w/w and 20% w/w.

#6